

As stated in MPEP 2163.07 (page 2100-173),

“An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of error in the specification, but also the appropriate correction. *In re Oda*, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971).”

Applicants submit that the reasoning expressed in that paragraph for corrections to the specification is equally applicable to corrections to the drawing, so that the amendment to Figure 5 does not constitute new matter.

On the Examiner's approval of the amendment, a replacement sheet of drawing will be provided.

#### **The amendment to the claims**

Added claims 26-28 are fully supported by the application as filed and the original Letters Patent and involve no new matter, because the compound of claim 26 is TER16998, which is the compound whose structural formula is shown in Figure 2D and the synthesis of which is disclosed in the Letters Patent at Example 4 (column 13, lines 18-25). Claim 27 is supported because it simply claims the use of TER16998 to lower blood glucose in a diabetic subject and parallels, for example, claim 21. Because TER16998 is disclosed as having a pharmaceutical utility, namely the treatment of diabetes, a pharmaceutical composition containing it is inherent; further, Example 5 discloses the administration of TER16998 in the db/db mouse model, where the compound was administered in a vehicle (i.e. as a pharmaceutical composition) because the vehicle was administered as a control. Claim 28 is thus supported.

Applicants note that the original Letters Patent or a statement as to its loss or inaccessibility must be received before allowance of this reissue application; and this matter will be dealt with in due course.

Applicants note their obligations under 37 CFR 1.178(b) with respect to notification of prior or concurrent proceedings. No such proceedings exist.

Applicants note their obligations under 37 CFR 1.56 with respect to duty of disclosure. An Information Disclosure Statement will be filed shortly, and the Examiner is respectfully requested to contact the undersigned attorney if the Information Disclosure Statement has not reached the file before she takes up the case for further action.

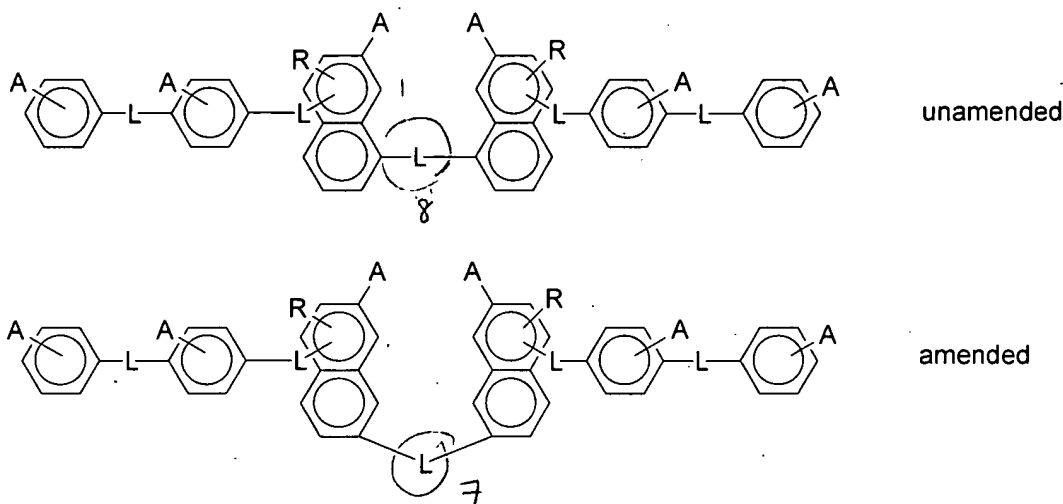
The specification was objected to; and claims 1-25 were rejected under 35 USC 251 and for double patenting. The objection and rejections are respectfully traversed.

#### **The objection to the specification and 35 USC 251 rejection (new matter)**

The amendment filed in the reissue application was objected to as containing new matter in violation of 35 USC 132, and claims 1-25 as amended were rejected under 35 USC 251 as being based on new matter; with the Examiner reasoning that the newly drawn structures are of positional isomers of the compounds of the formulae in Patent No. 5,851,988 and that the patent does not provide adequate written description for the newly submitted positional isomers.

Applicants respectfully disagree. Applicants agree that formulae (1) and (1B) have been amended to replace the positional isomers shown in the unamended formulae with different positional isomers; however, Applicants disagree that the amendment constitutes new matter.

A comparison of formula (1) unamended and amended is as follows (with the multiplicity of the R substituent on the naphthalene rings omitted and the term "linker" replaced by "L" for ease of drawing):



The comparison shows that if the "A" groups are considered as being at the 2-positions of their naphthalene rings, unamended formula (1) shows the linker as linking the 8-positions whereas amended formula (1) shows the linker as linking the 7-positions.

Applicants note that the patent in fact discloses no compounds of the genus seen in the unamended formula (1), but that it discloses subgenera of the genus seen in amended formula (1) — compounds of formulae (1A) and (1C) are both subgenera of the genus seen in amended formula (1), and that it discloses specific compounds falling within the genus seen in amended formula (1) — compounds such as TER3935 (Figure 2C), TER16998 (Figure 2D), TER17004 and TER17005 (both in Figure 2E) are all specific compounds within the genus seen in amended formula (1) where the linker between the naphthalene rings is a urea and the "A" group is a sodium sulfonate. What is more, the synthesis shown in Figure 5 is the synthesis of compounds where if the "A" groups are considered as being at the 2-positions of their naphthalene rings, the linker links the 7-positions, i.e. it is the synthesis of compounds of amended formula (1).

It is clear that compounds of formulae (1A) and (1C), and the compounds shown in Figures 2C, 2D, and 2E, which are stated in the patent as being compounds of formula (1) [the patent, at column 6, line 18 to page 7, line 23, states "Also preferred are embodiments wherein the compound of Formula (1) is selected from the group consisting of (formulae (1A), (1B), and (1C) drawn out) wherein each linker is independently either -N=N- or -NHCO-. Particularly preferred are compounds shown in FIGS. 2C, 2D and 2E herein] are not compounds of unamended formula (1), but are in fact compounds of amended formula (1).

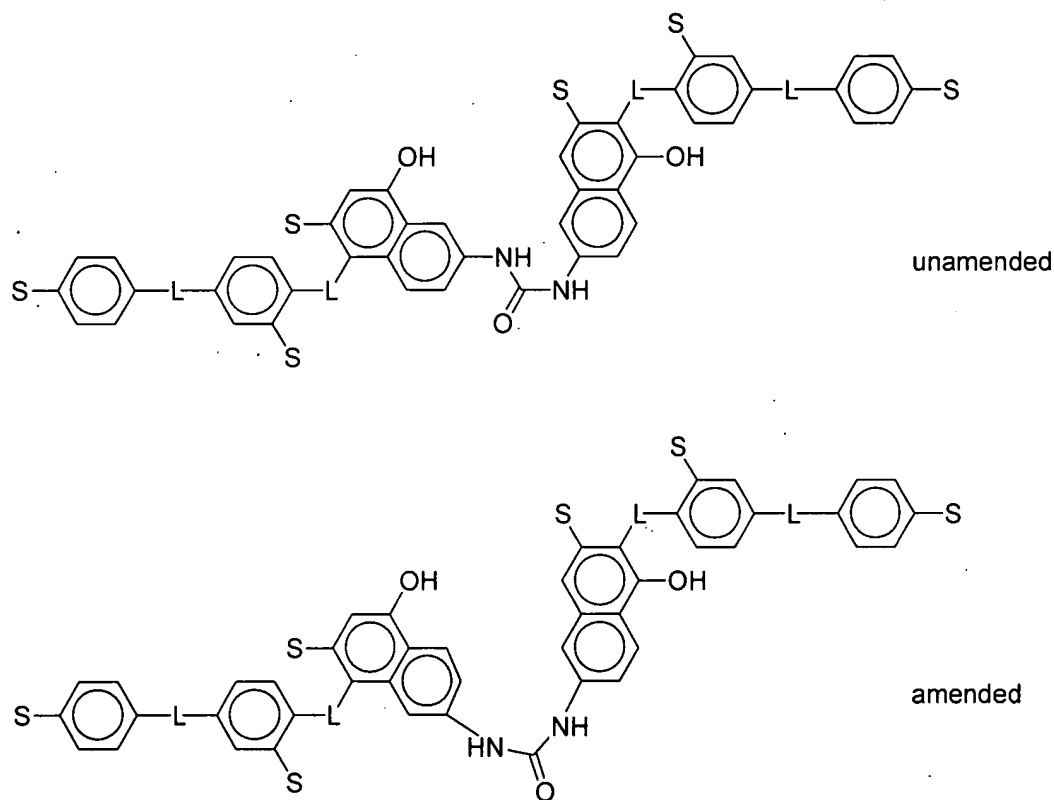
Applicants submit that unamended formula (1) contains an obvious error — the linker is shown as linking the 8-positions of the naphthalene rings. The error is obvious when it is considered that reading the unamended formula (1) as being correct results in two of the three stated subgenera of that generic formula, and all of the named compounds of the invention, not being compounds within

formula (1), and the disclosed synthesis not producing compounds of formula (1). The correction is equally obvious — redrawing of formula (1) so that the linker links the 7-positions of the naphthalene rings: the correction makes formulae (1A) and (1C) both properly subgeneric to the amended formula (1), makes the named compounds of the invention compounds of the amended formula (1), and makes the disclosed synthesis into the synthesis of compounds of formula (1). No other correction achieves a suitable result.

Applicants therefore submit that the amendment to correct formula (1) is the correction of an obvious error and does not constitute new matter because one of ordinary skill in the art would recognize the existence of error and the appropriate correction, following *In re Oda*.

With respect to formula (1B), the issue is similar.

A comparison of formula (1B) unamended and amended is as follows (with the multiplicity of the  $\text{SO}_3^-$  substituents designated solely by "S" and the term "linker" replaced by "L" for ease of drawing):



The comparison shows that if the "S" ( $\text{SO}_3^-$ ) groups are considered as being at the 2-positions of their naphthalene rings, unamended formula (1B) shows the left-hand naphthalene ring as having the urea linker in the 6-position whereas amended formula (1B) shows it in the 7-position (it is in the 7-position on the right-hand naphthalene in both the unamended and amended formula).

Applicants note that the patent in fact discloses no compounds of the genus seen in the unamended formula (1B), but that it discloses a specific compound falling within the genus seen in amended formula (1B) — TER16998 (Figure 2D) is the hexasodium salt of a specific compound within the genus seen in amended formula (1B) where the linkers are diazo groups. What is more, the synthesis

shown in Figure 5 is the synthesis of compounds where if the "S" groups are considered as being at the 2-positions of their naphthalene rings, the linker links the 7-positions, i.e. it is the synthesis of compounds of amended formula (1B).

Applicants also note that the genus seen in unamended formula (1B) is in fact not a subgenus of formula (1), either unamended or amended.

Applicants submit that unamended formula (1B) contains an obvious error — the left-hand naphthalene is shown as having the urea linker at the 6-position. The error is obvious when it is considered that reading the unamended formula (1B) as being correct results in formula (1B) not being a subgenus of formula (1), a named compound not being a compound within the subgenus of formula (1B), and the disclosed synthesis not producing compounds of formula (1B). The correction is equally obvious — redrawing of formula (1B) so that the urea linker links the 7-positions of the naphthalene rings: the correction makes formula (1B) subgeneric to the amended formula (1), makes TER16998 a compound of the amended formula (1B), and makes the disclosed synthesis into the synthesis of compounds of formula (1B). No other correction achieves a suitable result.

Applicants therefore submit that the amendment to correct formula (1B) is the correction of an obvious error and does not constitute new matter because one of ordinary skill in the art would recognize the existence of error and the appropriate correction, following *In re Oda*.

Withdrawal of the objection and rejection is requested.

#### **The double patenting rejection over US Patent No. 5,830,918**

Claims 1, 2, and 6-9 were rejected for obviousness-type double patenting over claims 1, 2, and 6-9 of US Patent No. 5,830,918. The Examiner reasons that although the claims are not identical, they are not patentably distinct because the claims of the patent encompass the compounds of the methods of this application when the linker is -NHCO- and  $m=0$ , i.e. that the compounds used in this application are a species of the genus of the compounds of the patent.

A terminal disclaimer over US Patent No. 5,830,918, and the required fee, are enclosed herewith.

Withdrawal of the rejection is requested.

#### **The provisional double patenting rejection over US Application No. 09/999,762**

Claims 1-4 and 6-14 were provisionally rejected for obviousness-type double patenting over claims 14-17 and 19-23, and claims 5 and 15 were provisionally rejected under 35 USC 101 as claiming the same invention as claim 25, of US Application No. 09/999,762.

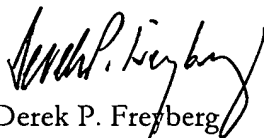
An Office Action was mailed in Application No. 09/999,762 on September 24, 2002, and was not responded to. Application No. 09/999,762 is therefore abandoned and the provisional double patenting rejections are therefore moot.

Withdrawal of the rejections is requested.

**Conclusion**

Entry of the amendment, and allowance of claims 1-28, are respectfully requested.

Respectfully submitted,



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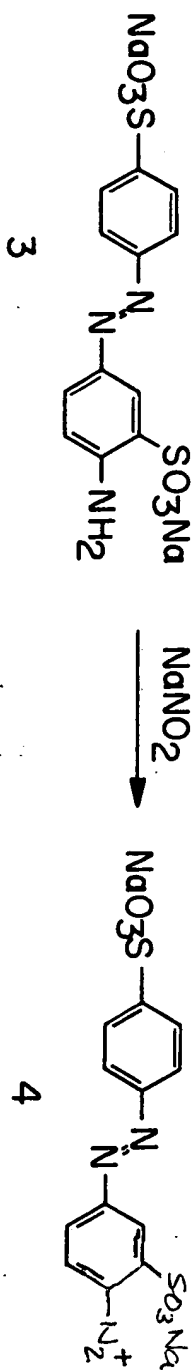
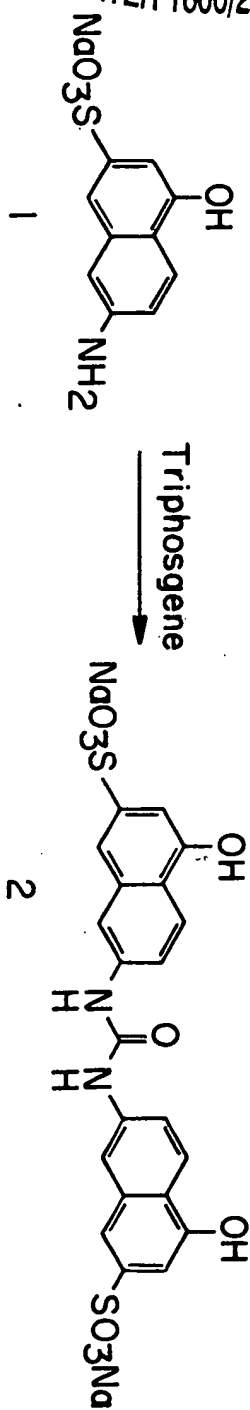
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mixture, including TER 16998

FIG. 5 (Amended)